

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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THERESA PITMAN, Individually and :  
On Behalf of All Others Similarly :  
Situating, :

Plaintiff, :

-against- :

IMMUNOVANT, INC. f/k/a HEALTH :  
SCIENCES ACQUISITIONS :  
CORPORATION, RODERICK WONG, PETER :  
SALZMANN, FRANK M. TORTI, ANDREW :  
FROMKIN, DOUGLAS HUGHES, GEORGE :  
MIGAUSKY, ATUL PANDE, ERIC :  
VENKER, SVB LEERINK LLC, LIFESCI :  
CAPITAL LLC, CHARDAN CAPITAL :  
MARKETS LLC, GUGGENHEIM :  
SECURITIES, LLC, ROBERT W. BAIRD :  
& CO. INCORPORATED, and ROIVANT :  
SCIENCES LTD., :

Defendants. :

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**MEMORANDUM AND ORDER**

21 Civ. 918 (KAM) (VMS)

**Vera M. Scanlon, United States Magistrate Judge:**

The Court has reviewed the three motions to dismiss the second amended complaint, which, in brief, argue that Plaintiff's second amended complaint should be dismissed because it is factually insufficient and legally insufficient. See ECF Nos. 60-62, 64-65, 68, 72-75. The Court has also considered Plaintiff's request for leave to amend the second amended complaint to add, inter alia, information about the Defendant Immunovant's former employee on whom Plaintiff relies. For the reasons discussed below, the Court grants Plaintiff's motion to

file a third amended complaint to address the facts that Plaintiff proposes be added about the Immunovant former employee, the factual issues identified below (if Plaintiff agrees with Defendants) and any other issues of concern to Plaintiff raised by the three motions. The Court finds the three pending motions to dismiss as moot in light of this grant of the motion to amend. By 2/17/23, the parties are to submit a proposed schedule as to the filing of the third amended complaint and as to the briefing of the anticipated motions to dismiss.

This Order assumes the parties' familiarity with the submissions that have been made to date in the case.<sup>1</sup> On the motions to dismiss, the Immunovant Defendants filed the lead briefs, ECF Nos. 60-62, 72, which were supported by the Underwriter Defendants, ECF Nos. 64, 65 (see footnote 1), 73 (see footnote 1), and Roivant, ECF Nos. 68 (see page 1), 74, 75. The Underwriter Defendants and Roivant also made arguments on their own behalf. ECF Nos. 64-65, 68, 73-74. Plaintiff opposed at ECF No. 71.

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<sup>1</sup> The procedural history of the pleadings is set forth in the stipulation and proposed order dated 3/2/22. See ECF No. 36. The Court so-ordered the parties' stipulation to the filing of the operative amended complaint, which was filed on 3/15/22. See ECF Order 3/7/22; ECF No. 44.

**I. Alleged Factual Deficiencies In The Second Amended Complaint Identified By Defendants**

Defendants together allege that Plaintiff's second amended complaint is factually deficient in the following ways:

1. Plaintiff does not sufficiently allege facts to make out the claim that elevated cholesterol was a known "anticipated risk" at the time the IMVT-1401 trials were designed or at the time the challenged statements were made. See ECF No. 61 at 14 n.11, 15-16 (" . . . it alleges no facts demonstrating that increased cholesterol was an 'anticipated risk'"), 19 (" . . . Plaintiff has not plausibly pled that increased cholesterol was an 'anticipated risk,'" ), 20, 22-23, 30, 32 ("[[T]he [Amended Complaint] contains no well-pled facts to support Plaintiff's theory that increased cholesterol was an 'anticipated risk' during the putative class period."), 37; ECF No. 72 at 1, 5 ("the notion that elevated cholesterol was an 'anticipated risk'"), 7-8, 20; see also ECF No. 65 at 16 ("First, Plaintiff does not plead facts showing that there was an 'anticipated risk' that IMVT-1401 would cause heightened cholesterol at the time of the September 2020 Offering." (emphasis removed)), 23 ("

. . even as Plaintiff concedes that the third party conducting the tests for cholesterol in the animal studies found only a 'minor increase in cholesterol'" (internal citation omitted)), 28; ECF No. 73 at 8.

2. Plaintiff does not sufficiently allege facts about the position that the cited animal studies demonstrate an "anticipated risk" of increased cholesterol. See ECF No. 61 at 2 ("there are no well-pled allegations that any animal study demonstrated a 'substantial risk' of elevated cholesterol in humans"), 20-23. As to the former Immunovant employee's interpretation of the results of the animal studies, they "are unreliable and deserve no weight" (a) because the amended complaint fails to state "whether the FE ["Former Employee"] had the necessary context or competence to even understand the scientific results he claims to report," id. at 20-21 (footnote omitted); (b) because the employee does not "offer any concrete facts to support his allegation that the animal studies clearly showed a substantial increase in the cholesterol of the animals that received IMVT-1401," id. at 21-22; ECF No. 72 at 1, 6 ("neither the [Amended Complaint] nor the Opposition provide the necessary details to support FE's after-the-fact opinions"); and (c)

because the employee's allegations "provide[] absolutely no basis to conclude that medical experts would expect cholesterol increases of 200-300% in monkeys to translate to similar cholesterol increases in humans," ECF No. 61 at 22 (footnote omitted). In the same vein, Plaintiff fails to allege sufficient facts to show that mild cholesterol increases were unsafe. See id. at 18.

3. As to 2(a) above, Plaintiff does not sufficiently allege facts about "FE", the unidentified former Immunovant employee upon whom Plaintiff relies as a source of information. See ECF No. 61 at 2 ("But the [Amended Complaint] fails to describe him at all—let alone 'with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged'" (internal citation omitted)), 20-21 (the FE is not "'described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged,' including by identifying their 'positions and/or job responsibilities'"); ECF No. 72 at 1; see also ECF No. 65 at 7 n.4 ("Plaintiff does not allege the confidential witness'

qualifications . . . ."). Without details as to the employee's qualifications and position held at Immunovant, the totality of the allegations in the amended complaint as to the former Immunovant employee's interpretation of the animal studies is unreliable.

4. As to 2(b) above, Plaintiff fails to allege sufficient facts to support the unidentified former Immunovant employee's interpretation of the research and data, including (a) the identification of which of the four toxicology studies the employee reviewed, see ECF No. 61 at 21 (internal citations omitted); (b) the provision of the data forming the basis for the employee's conclusions, see id. at 21-22 (internal citations omitted); (c) a calculation of the statistical significance of any results, see id. at 22 (internal citation omitted); see also ECF No. 65 at 7 n.4 ("Plaintiff does not allege . . . the statistical methodology that he/she used to reach his/her opinion."); ECF No. 73 at 4-5; and (d) the basis for the former Immunovant employee's conclusions that the experts who prepared summaries of unidentified animal studies of IMVT-1401 came to erroneous conclusions,

see ECF No. 61 at 21-22; ECF No. 72 at 1, 5; see also ECF No. 65 at 7; ECF No. 73 at 5.

5. As to 2(c) above, Plaintiff fails to allege sufficient facts about the supposed errors arising from Immunovant's animal testing, given that the bases for Immunovant's selection of the specific species of monkey for testing was "the high degree of sequence homology to human FcRn and IMVT-1401's strong binding affinity for monkey FcRn," as opposed to "shared attributes for cholesterol." ECF No. 61 at 22 n.17 (internal citation and quotations omitted). Plaintiff does not allege sufficient facts as to whether and why any such shared attributes would have warranted testing for and a comparative analysis of cholesterol levels in humans.
6. Plaintiff does not sufficiently allege that the cited scientific literature demonstrates an "anticipated risk" of increased cholesterol. See ECF No. 61 at 24-25. More specifically, two of the three cited articles fail to align with the issue alleged here, as (a) the subject of the first study was mice lacking any albumin, see id. at 25 ("observing that genetically modified mice that lack **any** albumin showed elevated levels of total cholesterol" (internal

citations omitted; emphasis in original)), and (b) cholesterol levels were controlled in the second study, see id. (studying the “link between lower levels of albumin and increased risk of heart attack while controlling for cholesterol levels” (internal citations omitted)). The third study is not informative about the supposed “anticipated risk” due to its lack of a conclusion about causation. See id. (“finding that mice without murine FcRn have lower levels of albumin and higher levels of cholesterol but making no finding regarding causation” (internal citations omitted)); ECF No. 72 at 1, 7 (alleging that the scientific articles on which Plaintiff relies do not discuss a causal relationship between albumin and cholesterol), 7 n.5-n.6, 20. Along these lines, Plaintiff relies on cholesterol monitoring performed by two of its competitors, one of which observed no effect on albumin levels, and the other of which observed no elevation in cholesterol levels. See ECF No. 61 at 25 n.18 (internal citations omitted); see also ECF No. 72 at 5, 8-9 (noting Plaintiff’s reliance on, inter alia, allegations about study protocols used by other companies without specifying the timing of those studies or the reasons for the cholesterol



monitoring). Plaintiff fails to allege sufficient facts to support the allegation that the competitors' research meant that cholesterol monitoring was clinically necessary in the Immunovant trial.

7. Plaintiff does not sufficiently allege facts to support the allegation that good clinical practices required testing as to cholesterol as an "anticipated risk." See ECF No. 61 at 19 (Plaintiff has not plausibly pled that "good clinical practices" require cholesterol testing); ECF No. 72 at 10.
8. Plaintiff does not sufficiently allege facts to support an inference of knowledge, especially as to the alleged "anticipated risk" of elevated cholesterol from the use of IMVT-1401. See ECF No. 61 at 16 ("failure to plead a strong inference of scienter"), 32-33 ("the AC contains no well-pled facts demonstrating that any Defendant actually knew IMVT-1401 might cause increases in cholesterol"), 37-38; ECF No. 72 at 1-2, 6 (arguing that the amended complaint does not allege knowledge of any "anticipated risk" as to cholesterol increases when the challenged statements were made); see also ECF No. 65 (" . . . Plaintiff does not adequately allege that Defendants knew of the 'anticipated risk' at the time

of the September 2020 Offering”), 16, 29 (“Yet Plaintiff has not alleged for purposes of its Securities Act claims that any ‘anticipated risk’ had occurred, let alone that Defendants knew of any ‘anticipated risk,’ at the time of the September 2020 Offering.”).

9. Plaintiff does not plead, as it argues in its Opposition, that elevated cholesterol was “merely a risk,” but instead pleaded in the second amended complaint that elevated cholesterol was a certainty that would materialize. See ECF No. 72 at 16. The facts alleged in the second amended complaint are thus inconsistent with the Opposition as to the significance of elevated cholesterol to the challenged statements and theory of gain for Defendants.
10. Plaintiff pleads “on information and belief” that Immunovant had failed to provide certain animal reports to the Food and Drug Administration (“FDA”) but does not include supporting facts about the alleged omission. See ECF No. 61 at 23; ECF No. 70 at 36.
11. According to Roivant, Plaintiff fails to plead sufficient facts as to the control-person claim against it. See ECF No. 68 at 5-7; ECF No. 74 at 1-3.

12. Plaintiff fails to plead sufficient facts supporting the elements of a scheme under Rule 10b-5(a) or (c). See ECF No. 61 at 13 n.10.

13. Facts used to support claims of fraud in the amended complaint have not been pleaded sufficiently under Fed. R. Civ. P. 9 and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. Sec. 78u-4(b)(1). Along this line, Plaintiff fails to sufficiently plead facts as to scienter as to Dr. Salzmann or other Immunovant employees. See ECF No. 61 at 39-40.

**II. Plaintiff's Request For Leave To Amend To, Inter Alia, Add Facts To The Complaint**

**a. Plaintiff's Proposed Additions To The Second Amended Complaint**

The major alleged factual deficiency that Plaintiff appears to acknowledge is the failure to include sufficient facts about the former Immunovant employee and the scientific basis for his alleged conclusions. At ECF No. 70, Plaintiff asks for leave to amend "should the Court find any defects in the [Amended Complaint]." Id. at 84; see id. at 23. The lead reply brief correctly points out that Plaintiff's Opposition Memorandum of Law at ECF No. 70 "attempts to introduce new facts not alleged in the [Amended Complaint]." See ECF No. 72 at 2, 5 ("The Opposition, however, effectively concedes that the [Amended

Complaint] does not contain sufficient facts to support FE's knowledge or reliability, and instead proffers additional facts Plaintiff could allege if granted leave to amend." (emphasis in the original)).

As to the FE's qualifications and position with Immunovant, Plaintiff suggests that it be given leave to add information such as the following to the second amended complaint:

For example, Plaintiff can allege FE was hired by Immunovant after two decades of experience in preclinical drug development, and worked as a senior employee in Immunovant's Non-Clinical Development group from the end of 2019 until after the Class Period. FE has a pathology background with a specialization in cardiovascular diseases and is a board-certified toxicologist. Immunovant hired FE to be involved with non-clinical strategies and the design of non-clinical study profiles.

FE had oversight regarding the design, monitoring, data analysis, and reporting of nonclinical study profiles and directed nonclinical strategies necessary to progress drug candidates from preclinical development to clinical trials. FE paid attention to whether a drug candidate had negative impacts. FE had experience with regulatory submissions, general toxicology, and safety pharmacology.

ECF No. 70 at 23-24.

As to the scientific basis for the FE's conclusions, the Opposition Memorandum of Law includes the following statement:

Third, Immunovant's preclinical animal studies revealed substantial increases in cholesterol in the animals tested with IMVT-1401. ¶¶70-72. According to a former Immunovant employee ("FE"), the underlying data from each of Immunovant's pre-clinical animal studies made it abundantly clear that animals which received IMVT-1401 experienced substantially increased

levels of cholesterol compared with those which did not receive IMVT-1401. ¶70. In fact, FE described the increases for those animals as 200 to 300 percent higher than the control group animals which did not receive the drug. Id.

ECF No. 70 at 5 (emphasis removed). This information is included in the second amended complaint and relied on by Plaintiff, but supporting information as to these facts is not provided in the second amended complaint. Plaintiff further suggests that it be given leave to add the following additional information in a third amended complaint:

In early January 2021, patients treated with IMVT-1401 during a Phase 2b clinical trial displayed increased cholesterol levels and the Principal Investigator notified IMVT-1401's clinical trial doctor regarding this issue. The Principal Investigator initiated an alert and the Internal Monitor advised the rest of the team and Defendant Salzmann. FE was tasked with reviewing each of Immunovant's completed preclinical animal studies to determine whether they showed an increase in total cholesterol levels in animals.

FE reviewed the toxicology studies obtained from the animals, reports, and data and observed significant increases in cholesterol levels in animals which received the drug compared to the control group - some animals displaying increases 200-300% higher than normal. FE provided a summary of findings to the then-Chief Medical Officer who relayed the information to other members of senior management of Immunovant.

ECF No. 70 at 24.

**b. Some Information About A Confidential Informant Upon Whom A Plaintiff Relies Should Be Included In A Securities Complaint**

"The Second Circuit has held that a plaintiff may rely on confidential witnesses so long as allegations in the complaint

are sufficient to 'provide an adequate basis for believing that the defendants' statements were false.'" Haw. Structural Ironworkers Pension Tr. Fund v. AMC Entm't Holdings, Inc., 422 F. Supp. 3d 821, 850-51 (S.D.N.Y. 2019) (quoting Novak v. Kasaks, 216 F.3d 300, 314 (2d Cir. 2000)). The plaintiff must describe the confidential sources "with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." Novak, 216 F.3d at 314; see Altimeo Asset Mgmt. v. Qihoo, 360 Tech. Co., 19 F.4th 145, 148 (2d Cir. 2021) (reversing dismissal of securities complaint, which relied on several sources, including a confidential witness who worked in the defendant's public relations department for three years, reported to a senior editor in the department, and attended a department meeting where a defendant directed the attendees not to reveal publicly certain information upon which complaint was based); see also Oklahoma Firefighters Pension & Ret. Sys. v. Six Flags Ent. Corp., 58 F.4th 195, 208 (5th Cir. 2023) (district court should have given minimal discount to confidential source in considering motion to dismiss securities class action about amusement park business where complaint referred to witness's unique and significant corporate title; complaint detailed that witness was "responsible for overseeing" construction of subject parks and reporting internally on progress, worked onsite, and

attended meetings with relevant personnel; and witness's account was supported by photo of project site showing essentially no construction); Luczak v. Nat'l Beverage Corp., 812 F. App'x 915, 924 (11th Cir. 2020) (on a motion to dismiss, district court should not have discounted the confidential sources where the complaint "identifie[d] each confidential witness's job, the time the witness spent in that job, and the relevance of the witness's job to the allegations"). "Additionally, a plaintiff must also allege that the confidential sources would have known what information was communicated to senior executives." Haw. Structural Ironworkers, 422 F. Supp. 3d at 851 (internal quotations omitted); KBC Asset Mgmt. NV v. DXC Tech. Co., 19 F.4th 601, 609-10 (4th Cir. 2021) (dismissing securities class action where complaint based scienter allegations in significant part on statements made by confidential witnesses who were former employees of information technology company, but complaint did not allege that confidential witnesses, who were several levels removed from the company's executive team, ever spoke with the executives about their concerns).

### **III. The Court Grants The Request For Leave To Amend**

Under Fed. R. Civ. P. 15(a), leave to amend "shall be freely given when justice so requires." Rule 15(a) is interpreted liberally. The Second Circuit Court of Appeals has held that a district court may abuse its discretion if it fails

to allow a plaintiff to amend a complaint when a plaintiff has not had an opportunity to amend a complaint and has offered to amend the complaint, unless amendments would be futile. For example, in this case, the Court could rule on the motions to dismiss, either denying or granting them in whole or in part; if the motions to dismiss were granted, determine whether any amendments would be futile; and, if amendments would not be futile, grant Plaintiff leave to amend with the benefit of the Court's decision. See Ronzani v. Sanofi S.A., 899 F.2d 195, 198 (2d Cir. 1990) ("Since Ronzani had not previously been given leave to amend, and had offered to amend his complaint, we hold that the court abused its discretion in dismissing the complaint without leave to amend."); see also Lehmann v. Ohr Pharm., Inc., 830 F. App'x 349, 353-54 (2d Cir. 2020) (citing Ronzani to remand to the district court to state on the record whether to allow the plaintiffs to replead); Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 797 F.3d 160, 191 (2d Cir. 2015).

In determining whether to allow a plaintiff to amend the pleadings, the court may consider whether the plaintiff's counsel has informed the district court how the complaint's alleged defects would be cured. See Porat v. Lincoln Towers Cmty. Ass'n, 464 F.3d 274, 276 (2d Cir. 2006). For example, in securities class action litigation, courts have allowed plaintiffs leave to amend to add facts demonstrating scienter,



one of the alleged defects in Plaintiff's amended complaint. See, e.g., Francisco v. Abengoa, S.A., 559 F. Supp. 3d 286, 312 (S.D.N.Y. 2021) (granting leave to file third amended complaint even though plaintiff did not propose that it had newly discovered law or facts to offer); Thomas v. Shiloh Indus., Inc., No. 15 Civ. 7449 (KMW), 2018 WL 4500867, at \*1 (S.D.N.Y. Sept. 19, 2018) (dismissing complaint after plaintiff had opportunity to replead but failed to allege scienter sufficiently). If there is a possibility that a plaintiff may make sufficient amendments so that the pleading may survive a motion to dismiss, a court should consider granting leave to amend. See In re Sec. Cap. Assur. Ltd. Sec. Litig., 729 F. Supp. 2d 569, 603 (S.D.N.Y. 2010); see also Loreley Fin. (Jersey) No. 3 Ltd., 797 F.3d at 191.

"Where a plaintiff seeks to amend its complaint while a motion to dismiss is pending, a court 'may either deny [the] pending motion to dismiss as moot or consider the merits of the motion, analyzing the facts as alleged in the amended pleading.'" Pecou v. Bessemer Tr. Co., No. 22 Civ. 1019 (MKV), 2022 WL 3646210, at \*1 (S.D.N.Y. Aug. 24, 2022) (quoting Pettaway v. Nat'l Recovery Sols., LLC, 955 F.3d 299, 303 (2d Cir. 2020)); see Wilson v. Fabric Cellar, Inc., No. 20 Civ. 244S, 2021 WL 2942354, at \*2 (W.D.N.Y. July 13, 2021) (discussing interplay of motions to dismiss and motions to

amend, granting leave to amend a complaint to address subject matter jurisdiction and denying motion to dismiss as moot).

"Where the proposed amended complaint requires leave of court, 'the preferred course is to grant leave to amend even if doing so renders moot the motion to dismiss, rather than granting the motion to dismiss and rendering moot the motion for leave.'"

Thompson v. City of N.Y., No. 21 Civ. 8202 (MKV), 2022 WL 562358, at \*1 (S.D.N.Y. Feb. 24, 2022) (quoting Rheaume v. Pallito, No. 15 Civ. 135 (WKS) (JMC), 2015 WL 7300790, at \*2 (D. Vt. Oct. 22, 2015)); see Env't Sols. Assocs. Grp., LLC v. Conopoco, Inc., No. 20 Civ. 10699 (MKV), 2021 WL 2075586, at \*2 (S.D.N.Y. May 24, 2021) (granting the plaintiff leave to amend and denying the pending motion to dismiss as moot). "[G]ranting leave to amend is consistent with the liberal standard of Rules 15 and 21, and with the Second Circuit's 'strong preference for resolving disputes on the merits.'" Patterson v. Stanley, No. 16 Civ. 6568 (RJS), 2017 WL 11569235, at \*2 (S.D.N.Y. Sep. 27, 2017) (quoting Loreley Fin. (Jersey) No. 3 Ltd., 797 F.3d at 190)).

In this case, where Defendants allege that the second amended complaint suffers numerous factual deficiencies, as listed above, as well as legal deficiencies, and where Plaintiff proposes to amend the amended complaint to add facts about a confidential source upon which Plaintiff relies, the Court finds

that the better use of the parties' and the Court's resources is to have Plaintiff file a third amended complaint drafted with consideration to Defendants' motions to dismiss. See New Oriental Enter., PTE, Ltd. v. Mission Critical Sols. LLC, No. 20 Civ. 2327 (MKV), 2021 WL 930616, at \*3 (S.D.N.Y. Mar. 11, 2021) (granting motion to amend in fraud action, denying motion to dismiss as moot, and observing: "The Court is also mindful of judicial economy and preserving the parties' resources."). Considering the anticipated motions to dismiss against a third amended complaint would give the Court and the parties the best opportunity to identify with specificity the issues that Plaintiff would need to address, if any, in a fourth amended complaint.<sup>2</sup> See Arkansas Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co., 28 F.4th 343, 348 (2d Cir. 2022) (affirming Tung v. Bristol-Myers Squibb Co., No. 18 Civ. 01611 (MKV), 2020 WL 5849220, at \*1 (S.D.N.Y. Sept. 30, 2020)) (affirming dismissal

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<sup>2</sup> Granting this motion to amend at this stage does not waive Plaintiff's right to request another opportunity to make amendments if the Court were to grant Defendants' anticipated motions to dismiss in whole or part. Nonetheless, Plaintiff should keep in mind the guidance of the Second Circuit: "When a plaintiff was aware of the deficiencies in his complaint when he first amended, he clearly has no right to a second amendment even if the proposed second amended complaint in fact cures the defects of the first. Simply put, a busy district court need not allow itself to be imposed upon by the presentation of theories seriatim." Nat'l Credit Union Admin. Bd. v. U.S. Bank Nat'l Ass'n, 898 F.3d 243, 257-58 (2d Cir. 2018) (alteration, internal quotations, & citations omitted).

of putative class action against pharmaceutical company and its officers for alleging company mischaracterized experimental design of clinical trial for new lung cancer drug and overstated trial's likelihood of success in violation of securities laws where plaintiffs' second amended complaint was dismissed for largely the same reasons the court dismissed the first amended complaint); Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, No. 12 Civ. 3723 (RJS), 2016 WL 5719749, at \*8 (S.D.N.Y. Sept. 29, 2016) (on consideration of the amended complaint (after remand in Loreley Fin. (Jersey) No. 3 Ltd., 797 F.3d at 191), granting defendants' motion to dismiss in part and denying it in part); see also Nguyen v. Endologix, Inc., 962 F.3d 405, 420 (9th Cir. 2020) (in securities class action against medical device corporation for allegedly false or misleading statements as to likely government approval of device, where the plaintiff had previously been granted leave to amend and had subsequently failed to add the requisite particularity to its claims, affirming denial of motion to amend on dismissal of action). The grant of the request for leave to amend here does not prejudice Defendants, as these are the first such motions based on the merits of the complaint; there has been no undue delay because Plaintiff raised the request in its omnibus opposition to all three motions to dismiss; and the

proposed amendments, as well as any others Plaintiff may make, cannot be said to be futile at this early stage of the case.

For these reasons, the Court grants Plaintiff's request for leave to amend. The Court does not express any opinion as to whether the alleged deficiencies are grounds that would require dismissal of the second amended complaint, but rather simply gives Plaintiff the opportunity to address the issues raised by Defendants in a third amended complaint as Plaintiff sees fit. Given the grant of this motion to amend, the Court finds the three pending motions to dismiss as moot. See ECF Nos. 60-62, 64-65, 68, 72-75.

By 2/17/23, the parties are to submit a proposed schedule as to the filing of the third amended complaint and the briefing of the anticipated motions to dismiss.

Dated: Brooklyn, New York  
February 14, 2023

*Vera M. Scanlon*  
VERA M. SCANLON  
United States Magistrate Judge